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APPLICATION NO.	FI	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/620,061	07/14/2003		Eduardo Blumwald	529642000221	3324	
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MORRISON & FOERSTER LLP 425 MARKET STREET				KUBELIK	KUBELIK, ANNE R	
		CA 94105-2482		ART UNIT	PAPER NUMBER	
	,	,		1638		
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/620,061	BLUMWALD ET AL.				
Office Action Summary	Examiner	Art Unit				
	Anne R. Kubelik	1638				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) ☑ This 3) ☐ Since this application is in condition for allowan closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro					
Disposition of Claims						
4) Claim(s) 1-22 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) Claim(s) is/are allowed. 6) Claim(s) 1-22 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or						
Application Papers						
9)☐ The specification is objected to by the Examiner 10)☒ The drawing(s) filed on 14 July 2003 is/are: a)☒ Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the original of the content of the original of the correction of the original of the correction of the original of the original origin	☑ accepted or b) ☐ objected to be drawing(s) be held in abeyance. See ton is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa	ite				

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DETAILED ACTION

1. Claims 1-22 are pending.

- 2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.
- 3. The instant application claims priority to provisional application 60/395,670, filed 15 July 2002. However, this application does not have any of E. Blumwald, M. Apse, W. Snedden or G. Aharon as an inventor. Furthermore, the first line of the instant specification indicates, incorrectly, that 60/395,670 was filed 12 July 2002. Thus, priority to provisional application 60/395,670 is not granted.
- 4. Parent applications 10/155,535 (now US 6,936,750), filed 24 May 2002, and 09/271,584 (now US 7,014,875), filed 18 March 1999, do not provide support for claims to any non-naturally occurring non-halophyte plant comprising a tissue with an elevated level of sodium substantially in the vacuole when cultivated in high salt. Provisional application, 60/395,637, filed 12 July 2002, also does not provide support for such claims. Thus, the effective filing date for such claims is the filing date of the instant application, 14 July 2003.

Claim Objections

5. Claims 2-19 and 21-22 are objected to because of the following informalities:

In claims 2-19 and 22, line 1, there should be a comma before "wherein".

In claim 21, line 1, --, said method-- should be inserted before "comprising".

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A full review of the specification indicates that plants transformed with nucleic acids encoding Na⁺/H⁺ transporters are essential to the operation of the claimed invention. The claims, however, are drawn to any non-naturally occurring non-halophyte plant that accumulates sodium in its vacuoles; this encompasses mutant plants, plants transformed with nucleic acids encoding proteins other than Na⁺/H⁺ transporters, as well as plants transformed with nucleic acids encoding Na⁺/H⁺ transporters.

The specification describes the structures of some Na⁺/H⁺ transporters, but the structures that make them vacuolar Na⁺/H⁺ transporters are not described. The specification fails to describe nucleic acids encoding proteins other than Na⁺/H⁺ transporters that result in sodium accumulation in vacuoles and fails to describe any mutant plants.

The specification fails to describe nucleic acids that hybridize to SEQ ID NO:1 under the conditions recited in claim 14, and fails to recite a function for those nucleic acids.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species.

Hence, Applicant has not, in fact, described on-naturally occurring non-halophyte plants within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

8. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for plants transformed with a nucleic acid encoding SEQ ID NO:1, does not reasonably provide enablement for any non-naturally occurring non-halophyte plant that accumulates sodium in its vacuoles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to any non-naturally occurring non-halophyte plant that accumulates sodium in its vacuoles and a method for using it to lower salt content in soil. The claimed plant include those transformed with nucleic acids that encode vacuolar Na⁺/H⁺ transporters, including those that hybridize to SEQ ID NO:1.

The instant specification, however, only provides guidance for analysis of the Na⁺, K⁺, sugars, praline, protein, and nitrogen content in various plant parts of AtNHX1 (SEQ ID NO:2)

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transformed *Brassica napus*; plants grown in high salt had an increase in Na⁺ and proline and a decrease in K⁺ and sugars in leaves and roots (example 1); analysis of H⁺-dependent Na⁺ and K⁺ movement and ion, sugar and proline contents of high-salt grown AtNHX1 (SEQ ID NO:2) transformed tomato (example 2); prophetic expression of AtNHX1 in yeast (example 3).

The instant specification fails to provide guidance for non-naturally occurring non-halophyte plants that accumulate sodium in their vacuoles, wherein the plant is mutant or the plant is transformed with a nucleic acid encoding a protein other than a Na⁺/H⁺ transporter.

The instant specification fails to provide guidance for which amino acids of SEQ ID NO:2 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain vacuolar Na⁺/H⁺ transporter activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Making substitutions in proteins does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1). All these mutated proteins, however, would have at least 95% identity to the original protein. The nucleic acids encoding all these

mutated proteins, however, would hybridize under high stringency to the nucleic acids encoding the original protein.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that hybridize to SEQ ID NO:1. Making all possible single amino acid substitutions in an 538 amino acid long protein like that encoded by SEQ ID NO:1 would require making and analyzing 19⁵³⁸ nucleic acids; these proteins would have 99.8% identity to SEQ ID NO:2. Because nucleic acids that hybridize to SEQ ID NO:1 would encode proteins with many amino acid substitutions, many more than 19⁵³⁸ nucleic acids would need to be made and analyzed.

Guo et al (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Thus, making and analyzing proteins with many amino acid substitutions that also have vacuolar Na⁺/H⁺ transporter activity would require undue experimentation.

As the specification does not non-naturally occurring non-halophyte plants within the full scope of the claims, undue trial and error experimentation would be required to screen through the myriad of plants, to identify those with sodium accumulation in their vacuoles, if such plants are even obtainable.

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Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

The terms "elevated level" and "substantially" in claim 1 are relative terms that render the claim indefinite. The terms "elevated level" and "substantially" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What are the levels and location being compared to?

Claims 2-5 are indefinite in their recitation of "in a comparable naturally occurring plant". Any plant can be compared to any other. Does Applicant have a particular plant in mind?

Claims 6-7 are indefinite in their recitation of "in a comparable non-transgenic plant".

Any plant can be compared to any other. Does Applicant have a particular plant in mind?

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Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 12. Claims 1-9, 11-12 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaxiola (US 2002/0023282 A1, filed August 2000).

Gaxiola teaches *Arabidopsis* whole plants transformed with a construct comprising the 35S promoter operably linked to a nucleic acid encoding a H⁺ pyrophosphorylase, which plants accumulate cations in the vacuoles (¶61-68). The levels of sodium in these plants would be 2-20-fold higher when compared to at least some non-transgenic plants. Seeds from these plants were produced (¶61 and 82-83). The plants were grown in salty soil, then harvested and removed (¶75).

Claim Rejections - 35 USC § 103 / § 102

- 13. The following is a quotation of 35 U.S.C. 103(a), which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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14. Claims 1-9, 11-12 and 14-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Young et al (WO 91/06651).

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Young et al teach tobacco and *Arabidopsis* plants transformed with a gene encoding the Na⁺/H⁺ transporter *sod2*, and the resistance of these transgenic plants to LiCl (pg 28, paragraph 3, to pg 35). Young et al also teach that that these plants would be resistant to high sodium concentration (pg 9, paragraph 1).

Young et al teach tobacco and *Arabidopsis* plants transformed with a construct comprising the 35S CaMV promoter operably linked to a nucleic acid encoding the Na⁺/H⁺ transporter *sod2*, and the resistance of these transgenic plants to LiCl (pg 28, paragraph 3, to pg 35). Young et al also teach that that these plants would be resistant to high sodium concentration (pg 9, paragraph 1). These plants are non-naturally occurring non-halophytes, and the nucleic acid encoding *sod2* would comprise "a" nucleic acid of at least 2 nucleotides of the coding strand in SEQ ID NO:1. *sod2* would be a plant NHX transporter because it functions in a plant.

The rejection is made because the Examiner cannot determine whether the prior art plants possess characteristics that are not recited in the art, that is, whether sodium is accumulated substantially in the vacuole when the plant is cultivated in high salt and whether the nucleic acid encoding *sod2* would hybridize to SEQ ID NO:1 under the recited conditions. The Examiner does not have sufficient facts to determine whether the claimed plants are inherently the same as the prior art plants. In addition, the Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the claimed and prior art plants differ. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that

the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

15. Claim 22 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gaxiola (US 2002/0023282 A1, filed August 2000).

The teachings of Gaxiola are discussed above. The rejection is made because the Examiner cannot determine whether the prior art method possesses characteristics that are not recited in the art, that is a soil conductivity of at least 20 dS/M. The Examiner does not have sufficient facts to determine whether the claimed methods are inherently the same as the prior art methods. In addition, the Examiner cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the claimed and prior art methods differ.

Claim Rejections - 35 USC § 103

16. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (WO 91/06651).

The claims are drawn to canola or safflower plants transformed with "a" nucleic acid of the coding strand in SEQ ID NO:1 or a nucleic acid that would hybridize to SEQ ID NO:1 under the recited conditions.

The teachings of Young et al are discussed above. Young et al do not disclose canola and safflower transformed with the nucleic acid.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the non-naturally occurring non-halophyte plants as taught by Young et al, to

transform the nucleic acid into canola and safflower. One of ordinary skill in the art would have been motivated to do so because of the economic importance of those plants.

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Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim3 and 5-34 of U.S. Patent No. 6,936,750. Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding Arabidopsis Na⁺/H⁺ transporter AtNHX5, as claimed in the issued patent, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, as claimed in the instant application.

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19. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7,041,875. Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding Arabidopsis Na⁺/H⁺ transporter AtNHX1, as claimed in the issued patent, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, including plants transformed with a nucleic acid that hybridizes to SEQ ID NO:1, as claimed in the instant application.

20. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/617,623. Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding an Arabidopsis Na⁺/H⁺ transporter, as claimed in the copending application, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, including plants transformed with a nucleic acid that hybridizes to SEQ ID NO:1, as claimed in the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-11 and 18-21 of copending Application No. 10/617,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because oil crop plants, including canola and safflower transformed with

a nucleic acid encoding a Na⁺/H⁺ transporter, as claimed in the copending application, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, including canola and safflower, as claimed in the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 19-48 of copending Application No. 11/067,456. Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding a Arabidopsis Na⁺/H⁺ transporter AtNHX2, as claimed in the copending application, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, as claimed in the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17 and 19-48 of copending Application No. 11/067,558. Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding a Arabidopsis Na⁺/H⁺ transporter AtNHX2, as claimed in the copending application, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, as claimed in the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim17 and 19-48 of copending Application No. 11/065,977. Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding a Arabidopsis Na⁺/H⁺ transporter AtNHX4, as claimed in the copending application, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, as claimed in the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 19-20 of copending Application No. 10/520,497. Although the conflicting claims are not identical, they are not patentably distinct from each other because plants transformed with a nucleic acid encoding Arabidopsis Na⁺/H⁺ transporter AtNHX1, including plants transformed with a nucleic acid that hybridizes to SEQ ID NO:1, as claimed in the copending application, are species of the genus of non-naturally occurring plants with a tissue with an elevated level of sodium in their vacuoles when cultivated in high salt, including plants transformed with a nucleic acid that hybridizes to SEQ ID NO:1, as claimed in the instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

- 26. No claim is allowed.
- 27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne Kubelik, Ph.D. September 20, 2006

AMME KUBELIK, PH.D. PRIMARY EXAMINER